

**REMARKS**

***Status of the Claims***

No claims are being canceled, added or amended. Thus, a listing of the claims is not needed. Claims 1, 3 and 5-8 are pending in the present application. Applicants respectfully request the Examiner to reconsider the present application in view of the following remarks

***Issues under 35 U.S.C. § 103(a)***

Claims 1, 3, 5 and 6 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ueno *et al.* '388 (U.S. Patent No. 5,304,388) (see pages 5-8 of the Office Action). Also, claims 1, 3, 7 and 8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ueno *et al.* '388 in view of Nurmi *et al.* '473 (WO 02/04473) (see pages 8-9 of the Office Action). Applicants respectfully traverse and reconsideration is based on the following remarks. Overall, Applicants do not concede that a *prima facie* case of obviousness has been established with respect to either rejection.

**The Present Invention**

The present invention relates to a method of producing crystalline maltitol, comprising the steps of: feeding a high-concentration maltitol aqueous solution to a kneader so as to knead and cool it; cooling the produced plastic mass to solidify it; and pulverizing the solidified mass. More specifically, the present invention relates to the following two methods.

(i) First embodiment (crystallization of raw material maltitol aqueous solution by a concentration difference – pending claim 1)

As a first embodiment, the present invention is directed to the method for producing crystalline maltitol, wherein a first maltitol aqueous solution having a solid content of maltitol of 70 to 97 wt% and a temperature of 90 to 120 °C is fed to a kneader so as to knead and cool it. Then, there is a second feeding wherein a second maltitol aqueous solution having a solid content of 97.5 to 99.5 wt% and a temperature of 120 to 140 °C is fed to the kneader, with further kneading and cooling of the resulting mixture so as to produce a plastic mass. Then the produced plastic mass is cooled so as to solidify it, and then the solidified mass is pulverized.

(ii) Second embodiment (addition of water to reduce the concentration of raw material and crystallization by a concentration difference – pending claim 3)

As recited in claim 3, the present invention is also directed to a method for producing crystalline maltitol wherein a maltitol aqueous solution having a solid content of 97.5 to 99.5 wt% and a temperature of 120 to 140 °C is fed to a kneader so as to knead and cool it. Then, water is added to the kneader with further kneading and cooling of the mixture so as to produce a plastic mass. When the produced plastic mass is solidified, it is also pulverized.

Thus, the mentioned first embodiment and the second embodiment relate to a method of producing crystalline maltitol in the absence of seed crystals. Since the seed crystals are not required, an efficient method of producing crystalline maltitol with use of simple equipment are provided.

provided.

Claim 1 and Claims Dependent Thereon: Distinctions over Cited Modification of Ueno '388

Regarding the first embodiment (claim 1), the cited Ueno '388 reference discloses a method of producing powdery or granular crystalline maltitol by adding seed crystals to a maltitol aqueous solution and applying a shear force to the solution (see, e.g., column 2, lines 23-32). Thus, the addition of the seed crystals is essential and the invention of Ueno '388 differs in technical idea from the present invention wherein seed crystals are not added.

Still, in the Office Action, the Examiner states that the seed crystals disclosed by Ueno '388 correspond to the second maltitol aqueous solution in pending claim 1 of the present invention on the ground that the seed crystals have a purity of 80% or more and a water content of 5% or less (see sentence bridging pages 5-6 of the Office Action). However, the second maltitol aqueous solution in claim 1 of the present application is a liquid, does not contain a crystal (solid matter) and is not a seed crystal. Again, the present invention relates to a method of producing crystalline maltitol without adding seed crystals and therefore is clearly distinguishable from the method and materials disclosed in Ueno '388 wherein seed crystals are added. Thus, Applicants traverse this rejection.

In this regard, M.P.E.P. § 2143 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors of: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are

at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Second, the Examiner has to provide some rationale for determining obviousness, wherein M.P.E.P. § 2143 set forth some rationales that were set established in the recent decision of *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Here, Applicants respectfully submit that the *Graham* factors, including ascertaining the differences between the prior art and the claims that are at issue, are in Applicants' favor, and the rationale in combining the cited references is improper. For instance, seed crystals are added in the Ueno '388 reference, which is in contrast to the present invention. Thus, the instant rejection of claim 1 and all claims dependent thereon is improper.

The Examiner also states Ueno '388 discloses the addition of seed crystals of maltitol added during agitation at a temperature lower than 140°C (see page 5 of the Office Action). However, "a temperature lower than 140°C" is the temperature of the raw material of the maltitol aqueous solution in a stirrer, and not the temperature of the seed crystals to be added. Since the seed crystals serve to grow crystals therefrom as nuclei, they are added at a temperature lower than their melting point and are not molten by heating. Thus, it is evident that the second maltitol aqueous solution in claim 1 of the present application is added as a liquid having a temperature of 120 to 140°C and differs from the seed crystals of Ueno '388 in term of properties, temperature and function. Thus, under *Graham* and *KSR Int'l, supra*, this rejection has been overcome.

Also, the phrase "a solid content" in the present invention does not refer to the content of maltitol which is existing as solid matter in the aqueous solution. Instead, this term refers to the

content of solid matter (components other than water) that is dissolved in water. The maltitol aqueous solution of the present invention is an aqueous solution (liquid) containing no undissolved solid matter.

Accordingly, as described above, the claimed first embodiment (claim 1) completely differs from the invention of Ueno '388. The Ueno '388 reference fails to teach that crystalline maltitol can be produced by the first embodiment. Also, one of ordinary skill in the art would not have the proper reason or rationale to modify Ueno '388 to achieve the present invention since, e.g., Ueno '388 uses seed crystals. Therefore, this rejection has been overcome.

Claim 3 and Claims Dependent Thereon: Distinctions over Cited Modification of Ueno '388

Applicants understand that Examiner considers that the addition of the seed crystals corresponds to the addition of water in pending claim 3 of the present application because the seed crystals disclosed by Ueno '388 contain water in the amount of 5% or less. However, solid seed crystals are added in the Ueno '388 method, whereas what is added in the present application (claim 3) is only water. Seed crystals containing 5% or less of water are not called "water."

Further, in the invention in claim 3 of the present application, crystallization is carried out by a concentration difference (diluting the aqueous solution) produced by adding a small amount of water to the raw material of the aqueous solution. Thus, crystalline maltitol is produced efficiently from the single raw material without adding seed crystals.

As described above, the second embodiment of the present application (claim 3) completely differs from the invention of Ueno '388. The Ueno '388 reference fails to teach that

crystalline maltitol can be produced by the second embodiment. Therefore, this rejection has been overcome.

Distinctions over the Combination of Ueno '388 and Nurmi '473

The Examiner rejects the inventions in pending claims 1 and 3 in view of the disclosures of Ueno '388 and Nurmi '473. In the Office Action, the Examiner cites Nurmi '473 and explains that this secondary reference discloses a seeding method without adding seed crystals. However, as described above, both the first and second embodiments of the present application completely differ from the invention of Ueno '388 in constitution, function and effect and cannot be easily attained even by combining the disclosure Nurmi '473 with that of Ueno '388.

Regarding the disclosure in the secondary reference, Nurmi '473 discloses seeding by means of evaporation or ultrasonic waves as seeding means and using no seed crystals. In the case of evaporation, as a large amount of heat is required, the cost rises and the equipment becomes complicated. In the case of applying ultrasonic waves, a special device is required.

Meanwhile, in the present invention, crystalline maltitol is produced without adding seed crystals and without using a special device by a very simple method. That is, the present invention involves the preparation of two different kinds of raw materials (see claim 1 of the present application) or adding a small amount of water (claim 3). Therefore, the present invention differs from the invention of Nurmi '473 in seeding means, function and effect. In other words, one of ordinary skill in the art would still not achieve the present invention based on the disclosures in Ueno '388 (which uses seed crystals) and Nurmi '473.

Also, as described in claim 1 of Nurmi '473, a maltitol solution must be oversaturated for seeding by evaporation or ultrasonic waves. The first maltitol aqueous solution and the second maltitol aqueous solution in claim 1 of the present application and the first maltitol aqueous solution in claim 3 of the present application are unsaturated and not seeded by evaporation or ultrasonic waves. The conditions such as "a solid content of 70 to 90 wt% and a temperature of 90 to 120°C" and "a solid content of 97.5 to 99.5 wt% and a temperature of 120 to 140°C" specified in the present invention mean that these aqueous solutions are unsaturated and this is supported by the expression "The temperatures at which the raw materials are fed to the kneader are preferably temperatures at which maltitol crystals re not deposited" in the specification (p. 4, lines 18-20) of the present application. Thus, the present invention differs from Nurmi '473 in other ways and thus from the cited combination of references.

Applicants note that if an oversaturated maltitol aqueous solution is used as a raw material and this seeding is applied to the continuous kneader of the present invention, excessive crystallization will drastically proceed by seeding after supplying the raw material and the raw material injection port will be blocked. This is yet another reason as to why this rejection is improper.

Still, the Examiner states that Nurmi '473 discloses at page 6, lines 1-4 that the maltitol solution is additionally supplied into a crystallization apparatus. The solution is additionally supplied due to a reduction in the content of maltitol in the raw material solution caused by the crystallization of maltitol and it is just the supply of the raw material. However, as described above, the rejection of the first and second embodiments in view of Ueno '388 and Nurmi '473 is improper for several reasons. This is because, e.g., seed crystals are added in the Ueno '388

method, and Nurmi '473 discloses seeding by means of evaporation or ultrasonic waves. Regarding the Examiner's reasons for combining both references as stated in the Office Action, Applicants note that the rationale should be made explicit, *KSR Int'l, supra*, and the Examiner must interpret the reference as a whole and cannot pick and choose only those selective portions of the reference which support the Examiner's position. *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention."). Applicants respectfully submit that one of ordinary skill in the art would not make such a combination of references for the reasons set forth above. Thus, Applicants respectfully disagree with the conclusions set forth at page 9 of the Office Action.

Reconsideration and withdrawal of this rejection are respectfully requested.

### ***Conclusion***

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Marc S. Weiner (Reg. No. 32,181) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

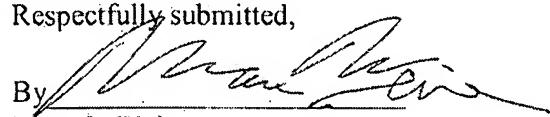
Application No. 10/517,451  
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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.147; particularly, extension of time fees.

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Respectfully submitted,

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